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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,556	10/11/2005	Nigel Dunn-Coleman	GC781-2-US	8864

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
07/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,556	DUNN-COLEMAN ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18 and 21-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/06 & 7/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. ***Election***

Applicants' election with traverse of Group I (claims 1-17 & 19-20) in reply filed 6/3/2008 is acknowledged.

The traversal is on the ground(s) that a search and examination of Groups I-VIII can be made without serious burden, see MPEP sections 803 and 808. Groups I-VIII all relate to an isolated polynucleotide of SEQ ID NO: 3 encoding beta-glucosidase of SEQ ID NO: 2 and Groups I-VIII could be searched together. In addition, the entire specification relates to beta-glucosidase, i.e., the same structure, i.e., the same function, for use in various industrial applications, i.e., the same utility. Thus, there would not be a serious burden on the Examiner to search Groups I-VIII and Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement.

Applicants' arguments are considered but not found to be persuasive because the technical feature linking Groups I-VIII appears to be that they all relate to β-glucosidase enzyme or the DNA encoding the same. However, it was explained in the prior Office Action that Groups I-VIII share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Further, searching of the sequence data bases as well as searches of commercial and US Patent data bases revealed several prior art works that support this determination. US Patents 7045332 teaches a DNA that encodes β-glucosidase from *Trichoderma reesei* - a fungus which reads on claim 1 and on the fragment language in claim 2(h).

Also searching for the invention of one group does not necessarily identify art for all the other groups, leading to additional searching. This additional searching as explained

above would therefore involve undue burden to the Examiner. The requirement is still deemed proper and is therefore made FINAL.

2. **Claims withdrawn** :

Claims 8 & 21-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. ***Continuation of prior application***

This application filed under 35 USC 119(e) lacks the necessary reference to the prior application. This application claims the benefit of US Provisional Application No. 06/424,784, filed 11/07/2002, should be entered following the title of the invention or as the first sentence of the specification. Also, the present status of all parent applications should be included.

4. Brief description to drawings in the specification (*see* page 6) must be corrected to indicate Figure 1A-1B (instead of Figure 1); and Figure 4A-4B (instead of Figure 4).

5. ***hyperlink***

The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, page 34 line 27 of the specification), is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

Applicant's cooperation is requested in correcting all *hyperlink(s)* which may have been added or were present in the original specification at the time of filing.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. Claims 1-17 & 19-20 are under consideration in this Office Action.

8. ***Claim Rejections - 35 USC § 112*** (first paragraph)

Written Description

Claims 1-17 & 19-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of polynucleotide or nucleic acid molecules wherein nucleic acid sequence encode a BGL6 polypeptide which is at least 85%, 90% or 95% identical to SEQ ID NO: 2 or the fragment of a DNA that hybridizes to the sequence of SEQ ID NO: 3 under defined conditions function.

The specification discloses the reduction to practice of one nucleic acid species within the claimed genus; specifically, the nucleic acid sequence of SEQ ID NO: 3 encoding protein having the amino acid sequence of SEQ ID NO: 3 and β-glucosidase activity. There are no drawings or structural formulas disclosed of any other nucleic acid encoding protein having the function of β-glucosidase. There is no teaching in

the specification regarding the 5-15% structure can be varied while retaining the ability of the protein to function as β-glucosidase. Further, there is no art recognized correlation between any structure (other than SEQ ID NO: 3) and the encoding protein of SEQ ID NO: 2 having β-glucosidase activity. Consequently there is no information about which nucleic acids or amino acids that can vary from SEQ ID NO: 3/SEQ ID NO: 2 in the claimed genus and still retain the catalytic activity.

Although the disclosure of SEQ ID NO: 3 and the encoding protein of SEQ ID NO: 2 having β-glucosidase combined with the knowledge would put one in possession of proteins that are at least 85%, 90% or 95% identical to SEQ ID NO: 2, and consequently vary the nucleic acid structure, the level of skill and knowledge in the art is such that one of ordinary skill would not be able to identify without further testing which of those proteins having at least 85%, 90% or 95% identity to SEQ ID NO: 2 (if any), and having the activity of β-glucosidase. Based on the lack of knowledge and predictability in the art, those of ordinary skill in the art would not conclude that Applicant was in possession of the claimed genus of nucleic acids or nucleic acids obtained by hybridization based on the disclosure of the single species of SEQ ID NO: 3, and further

use them in the making of vector, host cell and a in the recombinant expression of the protein.

9. ***Enablement Rejection***

Claims 1-17 & 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide sequence of SEQ ID NO: 3, encoding the β-glucosidase sequence of SEQ ID NO: 2, does not reasonably provide enablement for a nucleic acid sequence encoding a BGL6 polypeptide which is at least 85%, 90% or 95% identical to SEQ ID NO: 2 or the fragment of a DNA that hybridizes to the sequence of SEQ ID NO: 3 (claims 1-7) or the expression construct of claim 8 having varying homology with no defined function and which is further used in the preparation of vector, host cell and the recombinant expression of β-glucosidase (claims 9-17 & 19-20).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the

proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide [SEQ ID NO: 3] and encoded amino acid sequence of SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

Applicants have not sufficiently defined stringency conditions for hybridizations. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of the conditions which were actually used by Applicants in isolating the claimed polynucleotides which

hybridize to the disclosed sequences, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in the claims the exact nature of the hybridization conditions [high stringency conditions with prior basis in the specification] used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

Further, no guidance is provided to a nucleic acid sequence that hybridizes, under high stringency conditions to the sequence presented as SEQ ID NO: 3, or the complement or a fragment thereof, wherein said isolated polynucleotide encodes a polypeptide having the biological activity of a β-glucosidase.

The specification does not support the broad scope of the claims which encompass all modifications of DNA encoding SEQ ID NO: 2 by 5-15%, because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting β-glucosidase activity; (B) the general tolerance of β-glucosidase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any β-glucosidase residues with an expectation of obtaining the desired enzymatic or biological function capable of catalyzing a defined chemical reaction using known substrates; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the

scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature of the encoding DNA (or polynucleotide) encoding a specific β-glucosidase or fragments thereof having the desired enzymatic characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

10. ***Claim Rejections - 35 USC § 112*** (second paragraph)

(a) Claims 2-7 & 19-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (a-h), recite the phrase 'a nucleic acid sequence which encodes or is complementary to a sequence which encodes a BGL6 polypeptide'. Firstly, the uncommon abbreviation 'BGL6' must be spelled out at least the first time around. Secondly, the claim is indefinite because a complementary sequence of a nucleic acid can not encode BGL6 polypeptide. Correction is required.

Claims 3-7 & 19-20 are included in the rejection for failing to correct the defect present in the base claim(s).

(b) Claims 2-17 & 19-20, directly or a dependent manner recite the phrase 'derived from'. The claim is indefinite because the metes and bounds are unclear. Substituting the phrase with 'obtained from'.

11. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 & 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. USP 6,184,018 (or Fowler et al. USP 6,002,725). Instant claim 1(h), recite a nucleic acid sequence of SEQ ID NO: 3, or a fragment thereof or complement of. Claim 8 recite the phrase 'Complementary to a nucleic acid ..', which also interpreted here to mean complementary to any portion of the sequence (or fragment). Such a claim would read on di or tri nucleotides. Eye bailing of Li et al. cDNA sequence encoding β-glucosidase from a fungus shown in Table 1 (See column 23-25) reveal several such nucleotide matches between Applicants SEQ ID NO: 3 and Li's sequence.

Deleting 'fragment thereof' and the use of 'full complement' is suggested to overcome this rejection.

12. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 and 19-20 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 7,045,322 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The instant claims 1-7 have over-lapping scope issue and fragment or complement language with the cited patent.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

(PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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